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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,410	03/01/2004	Robert L. Martuza	066683-0198	4953

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	**PAPER NUMBER**
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/788,410	MARTUZA ET AL.	
	Examiner	Art Unit	
	Wu-Cheng Winston Shen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner prosecuting this case has changed. All inquiries directed to the application should be directed to examiner W. - C. Winston Shen.

Applicant's response received on 12/22/06 has been entered. Claims 1-15 are cancelled. Claims 16-29 are pending.

This application is a DIV of 09/625,509 07/25/2000 PAT 6,699,468 which is a DIV of 09/004,511 01/08/1998 PAT 6,139,834, which is a CIP of 08/478,800 06/07/1995 ABN, which is a DIV of 08/264,581 06/23/1994 PAT 5,585,096.

The series of parent applications of instant application listed above is based on the amendments of Specification filed on 9/7/2004.

Status of claims: Claims 16-29 are currently under examination.

Priority

1. In the response to Non-Final rejection mailed on 10/4/2006, Applicant pointed out that the Examiner omitted priority claim to U.S. Patent Application No. 08/264,581 (now Patent No. 5,585,096), filed June 23, 1994. The Examiner acknowledges that the information regarding omitted priority to U.S. Patent Application No. 08/264,581 (now Patent No. 5,585,096) was indeed submitted by applicants as amendments of Specification filed on 9/7/2004. It is noted that the specification of U.S. Patent Application No. 08/264,581 (now Patent No. 5,585,096), filed June 23, 1994 supports the claims of instant application (See 4th paragraph, column 4, and

4th paragraph, column 5, U.S. Patent No. 5,585,096). Therefore, the priority of claims of instant application is determined to be 06/23/1994.

Claim Objections

2. Claims 22-24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

It is noted that the following limitations "wherein said virus is targeted to a tumor cell of non-nervous tissue origin" (claim 22), " wherein said tumor cell is a neural tumor cell" (claim 23), and "wherein said virus is targeted to a specific tumor type with a tumor cell-specific promoter" (claim 24) are considered as the intended use of the virus recited in claim 16. The intended uses of the virus do not alter the structures of the virus and the mechanism of viral infection, and accordingly the recited intended uses in claims 22-24 are given limited patentable weight.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Previous rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because claim 20 recites that the HSV is "G207", is ***withdrawn*** because

applicants provided exemplary references in the research filed of HSV (Herpes Simplex Virus) indicating that G207 is a well established HSV viral construct, which refers to an oncolytic HSV with deletions at both γ(1) 34.5 loci and a LacZ gene insertion inactivating the HSV ribonucleotide reductase.

4. Claims 16-29 are ***newly rejected*** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "an alteration, relative to *wild type*, in γ34.5 gene" fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is known in the art at the time of filing of instant application that there are variations in viral genome between different strains or isolates of a given virus as a result of spontaneous and/or induced mutations. Therefore, in the absence of further clarification, it is unclear which virus strain or isolate should be considered as wild type as recited in claim 16. Claims 17-29 depend from claim 16.

Claim 24 recites the limitation "wherein said virus is targeted to a specific tumor type with a tumor cell-specific promoter" is vague and indefinite because a promoter is not targeted to a cell as recited.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Previous rejection of claims 16-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Martuza et al. (US Patent 5,85,096 Dec 1996) is ***withdrawn*** because the priority date is instant application is determined to be 06/23/1994, which is the filing date of Martuza et al. (US Patent 5,85,096 Dec 1996).

Previous rejection of claims 16-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Martuza et al. of WO 96/00007 (1/1996) is ***withdrawn*** because the priority date is instant application is determined to be 06/23/1994, which is the filing date of Martuza et al. (US Patent 5,85,096 Dec 1996).

6. Claims 16-18, 22-24, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chou et al. (Chou et al., Mapping of herpes simplex virus-1 neurovirulence to $\gamma_1$34.5, a gene nonessential for growth in culture. *Science* 250(4985): 1262-6, 1990).

Chou et al. teach that four recombinant HSV-1 viruses (Herpes Simplex Virus 1) were genetically engineered to test the function of the $\gamma_1$34.5 gene. These were (i) a virus from which *both copies of the gene were deleted*, which is encompassed by claim 17 of instant application, (ii) a virus containing a stop codon in both copies of the gene --- which is encompassed by claim 18 of instant application, (iii) a virus containing after the first codon an insert encoding *a 16-amino acid epitope known to react with a specific monoclonal antibody,* which is encompassed by claim 16 of instant application, and (iv) a virus in which the deleted sequences were restored.

With regard to claims 22-24 of instant application, it is noted that the following recitations "wherein said virus is targeted to a tumor cell of non-nervous tissue origin" (claim 22), " wherein said tumor cell is a neural tumor cell" (claim 23), and "wherein said virus is

targeted to a specific tumor type with a tumor cell-specific promoter" (claim 24) are considered as the intended use of the virus recited in claim 16. The intended uses of the virus do not alter the structures of the HSV and the mechanism of viral infection, and accordingly the recited intended uses in claims 22-24 are given limited patentable weight. In this regard, it is known in the art at the time of filing of instant application that HSV can infect, primarily but not exclusively, neural cells both *in vitro* and *in vivo* (for instance, causing encephalitis --- inflammation of the brain --- as cited by Chou et al. 1990), and thereby natural promoters of HSV can express genes in a neural tumor cell as well as in tumor cell of non-nervous tissue origin, which is encompassed by claim limitation recited in claim 22-24.

With regard to claim 29 of instant application, a pharmaceutically acceptable vehicle reads on water, which is encompassed by the teachings of Chou et al.

Thus, Chou et al. clearly anticipates claims 16-18, 22-24, and 29 of instant invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) or 1.321 (d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Previous provisional rejection of claims 16-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-18 of copending Application No. 10/748,233 is ***maintained*** for the reasons of the record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to the same herpes virus construct. In each case the claims as a whole set forth a herpes virus comprising an alteration in γ34.5, a heterologous gene of interest and an alteration in the ribonucleotide reductase gene.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Previous provisional rejection of claims 16-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-39, 43-46 of copending Application No. 11/097,391 is ***maintained*** for the reasons of the record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to the same herpes virus construct. In each case the claims as a whole set forth a herpes virus comprising an alteration in 3,34.5, a heterologous gene of interest and an alteration in the ribonucleotide reductase gene. For example claim 10 and claim 39 both set forth that the HSV is G207.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
Art Unit 1632

PETER PARAS, JR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600